

ADAM SMITH
9TH DISTRICT, WASHINGTON
116 CANNON BUILDING
WASHINGTON, DC 20515
(202) 225-8901

DISTRICT OFFICE:
3500 PORT OF TACOMA ROAD E., SUITE 306
TACOMA, WA 98424
(253) 926-6683
TOLL FREE 1-888-SMITH09
e-mail: adam.smith@mail.house.gov

Congress of the United States
House of Representatives
Washington, DC 20515-4709

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April 15, 1999

Dr. Patricia S. Schwartz
Center for Food Safety and Applied Nutrition
(HFS 401)
Food and Drug Administration
200 C Street Southwest
Washington, DC 20204-0001

Re: Performance Standard for *Vibrio vulnificus*; Request for Comments
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
[Docket No. 98P-0504]

Dear Dr. Schwartz,

I am writing you because I would like to submit my comments in regards to the FDA's Request for Comments on performance standards for *Vibrio vulnificus* and *Vibrio parahaemolyticus*. While I will not comment directly on those specific areas called for in the Federal Register, I do want to comment on the process of establishing policies and regulations for shellfish and the need for further research in establishing scientifically sound environmental parameters for *Vibrio vulnificus* and *Vibrio parahaemolyticus*.

My primary concern pertains to the process of establishing policies and regulations for shellfish. Specifically, I am concerned that the petition submitted to you by the Center for Science in the Public Interest has circumvented the Interstate Shellfish Sanitation Conference (ISSC) process by which policies and regulations for assuring shellfish safety are normally developed. In speaking with representatives of the West Coast shellfish industry, I know that they are concerned with protecting public health and have experienced some frustration with the ISSC process in the past in regards to the Gulf Coast's historical problems with *Vibrio vulnificus*. However, I still believe the ISSC process offers the most democratic solution to the many complex issues related to shellfish safety. I therefore urge you to carefully consider any comments that may come in, and to share these comments with the ISSC so that the deliberation process of the ISSC is not circumvented.

I also believe that further research is needed to establish scientifically sound environmental parameters for *Vibrio vulnificus* and *Vibrio parahaemolyticus*. On the West Coast, where *Vibrio parahaemolyticus* has been a problem, particularly for the past two uncommonly warm summers, the shellfish industry worked with their regulators to develop a control plan. That plan, put into place this past summer, appears to have been highly effective in reducing illnesses caused by these

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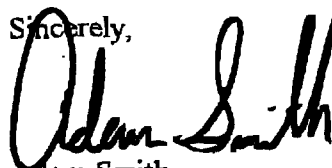
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bacteria. Since the plan also calls for data collection, while seemingly reducing illnesses simultaneously, it would appear a logical course of action to continue using the plan through the next two summers to better assess the situation.

Thank you for acknowledging my comments as you consider the most beneficial way to proceed in regards to *Vibrio vulnificus* and *Vibrio parahaemolyticus*.

Sincerely,

A handwritten signature in black ink, appearing to read "Adam Smith". The signature is fluid and cursive, with the first name "Adam" and last name "Smith" clearly distinguishable.

Adam Smith
Member of Congress

AS/mrc